IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Plaintiffs, v. MODERNA, INC. and MODERNATX, INC., Defendants.	C.A. No. 22-252-JDW
MODERNA, INC. and MODERNATX, INC., Counterclaim-Plaintiffs, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Counterclaim-Defendants.	[redacted] REDACTED - PUBLIC VERSION

MODERNA'S OPENING BRIEF IN SUPPORT OF ITS MOTIONS FOR SUMMARY JUDGMENT

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TABLE OF ABBREVIATIONS

Abbreviation	Full Description
"Moderna"	Collectively, Moderna, Inc. and Modernatx, Inc.
"Genevant"	Genevant Sciences Gmbh
"Arbutus"	Arbutus Biopharma Corp.
"Plaintiffs"	Collectively, Arbutus and Genevant
"the '069 patent"	U.S. Patent No. 8,058,069 (Ex. 2)
"the '668 patent"	U.S. Patent No. 8,822,668 (Ex. 3)
"the '651 patent"	U.S. Patent No. 9,504,651 (Ex. 4)
"the '359 patent"	U.S. Patent No. 8,492,359 (Ex. 5)
"the '435 patent"	U.S. Patent No. 9,364,435 (Ex. 6)
"the '378 patent"	U.S. Patent No. 11,141,378 (Ex. 7)
"Ratio Patents"	Collectively, the '069, '359, '668, '435 and '378 patents, of which only the '359, '435 and '378 patents remain asserted.
"C-34"	Contract No. 75A50120C00034 (Ex. 9)
"C-100"	Contract No. W911QY20C0100 (Ex. 1)
"MacLachlan"	U.S. Patent App. Pub. No. 2006/0008910 (Ex. 57)
"mol % range limitations"	Collectively, the cationic, non-cationic, conjugated lipid claim limitations recited in the Ratio Patents
"DOE"	doctrine of equivalents
"PTO"	U.S. Patent and Trademark Office
"'069 IPR"	*Moderna Therapeutics, Inc. v. Arbutus Biopharma Corp.*, IPR2019-00554 (P.T.A.B.).
"'435 IPR"	*Moderna Therapeutics, Inc. v. Protiva Biotherapeutics, Inc.*, IPR2018-00739 (P.T.A.B.).
"'069 Appeal"	*Moderna TX, Inc. v. Arbutus Biopharma Corp.*, No. 2020-2329 (Fed. Cir.).
"'435 Appeal"	*Moderna TX, Inc. v. Protiva Biotherapeutics, Inc.*, No. 2020-1184, -1186 (Fed. Cir.).
"LNP"	lipid nanoparticle

Abbreviation	Full Description
"Blenke"	Blenke et al., *Critical evaluation of quantification methods for oligonucleotides formulated in lipid nanoparticles*, 548 International J. Pharms. 793–802 (2018) (Ex. 60)

I. INTRODUCTION[1]

Plaintiffs (Arbutus and Genevant) filed this case in 2022, claiming that every single COVID-19 vaccine Moderna sold, regardless of whether it was made or sold in the U.S. or pursuant to a federal government contract, infringed six patents. Despite Plaintiffs' protestations, the case has since been narrowed—extraterritorial sales are out, and so are two of its six patents—but Plaintiffs continue to pursue claims and arguments that fail as a matter of law in pursuit of over $5 billion in damages. Moderna brings this motion to address three of those issues: (i) whether approximately $2.4 billion of Plaintiffs' damages claim against Moderna is barred under § 1498 because those vaccines were expressly made for the federal government, as the government contract makes clear; (ii) whether Plaintiffs' infringement claims under the doctrine of equivalents ("DOE") for the Ratio Patents (the '435, '359, and '378 Patents) are barred by prosecution history estoppel because Plaintiffs expressly narrowed their claims to disclaim the compositions they now contend infringe; and (iii) whether the expired '651 patent is indefinite because the claims require distinguishing "full encapsulation" of mRNA from "partial encapsulation" and there is no way to do that. The answer to each of these questions is yes, and Moderna's motion for summary judgment should be granted.

Section 1498. Before the pandemic, Moderna was a comparatively small biotech company in Cambridge, Massachusetts, pioneering a new class of medicines made of messenger RNA ("mRNA") for therapeutic and prophylactic uses, such as vaccines. Once the pandemic began, Moderna acted swiftly to provide the U.S. Government with vaccine supply—precisely as Congress envisioned when it enacted 28 U.S.C. § 1498(a) to encourage suppliers "to furnish what [is] needed by the government, without fear of becoming liable themselves for

[1] All emphasis added unless otherwise noted.

infringements to . . . the owners or assignees of patents." This important statutory protection, specifically incorporated into the C-100 Contract, covers all those who supply the U.S. Government with its authorization and consent. When § 1498 applies, the sole remedy lies in an action against the U.S. Government in the Court of Federal Claims. This case is no exception. Moderna supplied COVID-19 vaccine to the U.S. Government pursuant to a contract (specifically, the C-100 Contract), as part "of the national emergency response to . . . COVID-19[], for the United States Government . . . and the US population." In that contract, the Government expressly invoked its sovereign authority to "authorize[] and consent[] to all use and manufacture . . . of any invention described in and covered by a United States patent." And if that were not enough (it is), the Department of Justice submitted a statement, confirming that "Section 1498(a) . . . provides the exclusive remedy for any infringement occurring in the course of Moderna's performance of the '-0100 Contract." D.I. 49 at 2. After opposing Moderna's motion to dismiss, Plaintiffs were given every opportunity to litigate this issue. Despite the two expert reports they submitted (which should be excluded in any event), Plaintiffs cannot identify any materially disputed facts. Instead, they ask the Court to ignore binding Federal Circuit precedent and second-guess the Government's decision to enter into the contract with Moderna in the first place. Those are not material disputes of fact. As the Court noted in its motion to dismiss order, this § 1498 dispute should be resolved on summary judgment, Moderna's motion should be granted, and Plaintiffs may bring suit against the proper party (the U.S. Government) in the Court of Federal Claims.

Prosecution History Estoppel. Plaintiffs' patents are overbroad and cover a technology that has been known for decades— nucleic acid-lipid particles.[2] The Ratio Patents claim

[2] Nucleic acid is a broad family of chemical compounds, including various types of DNA and RNA. Messenger RNA (mRNA), as found in Moderna's COVID-19 vaccine, is a type of RNA. A "lipid particle" is "a lipid formulation that can be used to deliver an active agent . . . such as a nucleic acid." Ex. 2 ('069 Patent) at 11:4–6.

formulations of nucleic acid-lipid particles with four lipid components. The combination of those four lipid components with nucleic acids was not new when the patents were filed. Although the Ratio Patents emphasized the importance of having higher amounts of cationic lipid (i.e., 57 mol %), the patentee originally sought to claim far broader ranges than this allegedly novel, high-cationic lipid particle. The Examiner recognized that the overbroad lipid-component ranges the patentee was trying to claim ran headlong into the prior art and rejected the claims. This should have come as no surprise to Plaintiffs because the Examiner rejected the claims over another patent publication by the named inventor, Ian MacLachlan. So, to avoid the inventor's own prior work, Plaintiffs narrowed the ranges of lipid components by removing the word "about" from the claims. There is no dispute this narrowed the claims—Plaintiffs admitted as much during claim construction. And the Court likewise found that "[w]hen Plaintiff removed the phrase 'comprising about,' it . . . ***clearly disclaimed*** these broader ranges . . . ." D.I. 266 at 21. Plaintiffs, however, are now trying to go back on what they told the Examiner and the Court by arguing that accused vaccines with lipid components ***outside*** the claimed ranges infringe under the DOE. That argument is foreclosed as a matter of law by prosecution history estoppel, which serves an important purpose of ensuring the inventor does not "avoid the PTO's gatekeeping role and seek to recapture in an infringement action the very subject matter surrendered as a condition of receiving the patent." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734 (2002). To avoid the outcome that binding precedent dictates, Plaintiffs argue that their claim narrowing was only "tangential" to the alleged equivalents here. But that is wrong. The alleged equivalents involve the expansion of ***the same*** mol % ranges that the Examiner determined were overbroad during prosecution. Summary judgment on Plaintiffs' DOE claims for the Ratio Patents should therefore be granted.

Indefinite Claims. The '651 Patent is similarly directed to nucleic acid-lipid formulations and, as relevant here, the percentage of mRNA encapsulated by the lipids. During claim construction, both parties proposed constructions for the term "fully encapsulated." The '651 Patent identifies three distinct states of encapsulation: (1) fully encapsulated, (2) partially encapsulated, or (3) not encapsulated. Thus, the Court construed "fully encapsulated" to mean "***fully, as distinct from partially***" encapsulated. But there is no dispute that the patent fails to provide any means of differentiating "fully" from "partially" encapsulated. Plaintiffs' fact and expert witnesses likewise could not do so, and the known methods of measuring encapsulation at the alleged priority date of the '651 patent could lead to materially different results. "[A] patent must be precise enough to afford clear notice of what is claimed," thereby 'appris[ing] the public of what is still open to them.'" *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 909 (2014) (citation omitted). That is not the case here where the term at issue has no defined meaning. As such, the '651 Patent claims are invalid for indefiniteness.

II. NATURE AND STAGE OF THE PROCEEDINGS

On February 28, 2022, Plaintiffs filed a complaint (D.I. 1) against Moderna for patent infringement, accusing Moderna's COVID-19 vaccine of infringing six patents (the five Ratio Patents and the '651 patent). SOF ¶¶ 1–2. In May 2022, Moderna filed a partial motion to dismiss based on Plaintiffs' infringement allegations protected by § 1498. D.I. 17. The Court denied that motion, noting that the relevant C-100 Contract was heavily redacted and the issue could not be resolved without the "full and complete terms of the contract." D.I. 31 at 13. Instead, the Court suggested that where appropriate, "a § 1498(a) dispute should be resolved by summary judgment rather than on a motion to dismiss." *Id.* Plaintiffs were ordered to narrow their infringement allegations, and now assert three Ratio Patents (claims 7, 8, and 16 of the '435 patent, claims 7 and 12 of the '359 patent, and claims 2, 7, 13, 18, and 19 of the '378 patent) and the '651 patent

(claims 7, 9, 11, 13, and 14). SOF ¶¶ 1–2; D.I. 475.[3] Fact discovery and expert discovery are now closed. Summary judgment briefing is scheduled to complete on September 19, 2025, and *Daubert* briefing is scheduled to complete on December 5, 2025. Trial is set to begin March 9, 2026.

III. SUMMARY OF ARGUMENT

(1) If Plaintiffs believe doses of Moderna's COVID-19 vaccine provided to the Government pursuant to the C-100 contract infringe the Asserted Patents, they have sued the wrong party in the wrong court. Plaintiffs' claim against Moderna that the C-100 doses infringe the Asserted Patents is barred by the express terms of Moderna's C-100 contract with the Government that confirms that those doses were "for the Government" and "with the authorization or consent of the Government." Plaintiffs' sole remedy for its C-100-based infringement claims is against the U.S. Government in the Court of Federal Claims, and summary judgment here should be granted. *See* 28 U.S.C. § 1498.

(2) Plaintiffs admitted that they narrowed the asserted claims of the Ratio Patents during prosecution to avoid the Examiner's rejection over a prior art reference. Plaintiffs' DOE theories attempt to recapture portions of the territory surrendered during prosecution, and are thus barred by amendment-based prosecution history estoppel. *Festo*, 535 U.S. at 741.

(3) Additionally, during prosecution, Plaintiffs repeatedly and unmistakably tied the claimed invention of the Ratio Patents to "formulations having **increased** amounts of cationic lipid, e.g. one or more cationic lipids comprising from 50 mol % to 65 mol %[4] of the total lipid present in the particle." Ex. 75 (Aug. 11, 2011 – '069 PH) at 9 (emphasis in original). Therefore,

[3] Plaintiffs no longer assert the '069 and '668 patents. SOF ¶¶ 1–2; D.I. 475.
[4] Molar amount of a substance is the amount of that substance measured in moles. A mole is a unit of measurement to express amounts of a chemical substance. Molar percentage of a lipid in a mixture refers to the proportion of moles of a specific lipid relative to the total moles of all lipids.

argument-based prosecution history estoppel bars Plaintiffs' DOE arguments that accuse products with **decreased** amounts of cationic lipid (***less*** than 50 mol %).

(4) During claim construction, the Court construed the term "fully encapsulated" to mean "fully, as distinct from partially" encapsulated. But there is no accepted definition of "fully" and "partially" encapsulated mRNA in the field and no measurement method that can identify how much mRNA is "fully, as distinct from partially" encapsulated. As such, one of skill in the art would have no reasonable certainty of the scope of the asserted claims of the '651 patent, and thus, they are indefinite.

IV. STATEMENT OF FACTS

Moderna incorporates by reference its Statement of Undisputed Facts ("SOF").[5]

V. LEGAL STANDARDS

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Rule 56 "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322. "The moving party is 'entitled to a judgment as a matter of law' because the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof." *Id.* at 323.

[5] Pursuant to the Scheduling Order (D.I. 485), an accompanying Statement of Undisputed Facts is filed herewith. All exhibits are to the accompanying Declaration of Mark C. McLennan.

VI. PLAINTIFFS' INFRINGEMENT CLAIMS BASED ON SALES COVERED BY THE C-100 CONTRACT ARE BARRED UNDER § 1498

In March 2020, the U.S. Government declared a national emergency in response to the unprecedented public health crisis posed by the COVID-19 pandemic. SOF ¶¶ 3–4. Soon after, the Trump Administration initiated Operation Warp Speed (led by the Departments of Health and Human Services and Defense), through which the Government sought the help of private companies—and, here, Moderna in particular—to work together to develop and bring COVID-19 vaccines to the American public as quickly as possible. *Id.* ¶¶ 5–13.

In August 2020, Moderna and the U.S. Department of Defense (through the Army Contracting Command) entered into the C-100 Contract, under which Moderna agreed to provide millions of doses of COVID-19 vaccine "for the United States Government (USG) and the US population." Ex. 1 (C-100 Contract) at 302–03. In entering the contract, the Government recognized that it was not clear "whether or not these doses [of Moderna's COVID-19 vaccine] will be useable," but accepted that "risk" as "acceptable to the USG." Ex. 17 (DOD_000003510) at 515. Although the Government hoped the vaccine would "reduce SARS-CoV-2 transmission" and "mitigat[e] the impact of COVID-19 on the nation and its people," such an outcome was not guaranteed. Ex. 1 (C-100 Contract) at 302. In such circumstances, the Court need not and should not second-guess the Government's determination that it benefitted by procuring the contracted-for goods.

The C-100 contract itself explicitly outlined, in Sections A ("Solicitation/Contract Form") and C ("Descriptions and Specifications"), for example, its nature and scope (Ex. 1 at 285, 302):

> A.1. The U.S. Army Contracting Command – Aberdeen Proving Ground (ACC-APG), Natick Division has a requirement for up to 500 million SARS-CoV-2 mRNA-1273 Vaccine doses (100 μg) in support of Joint Program Executive Office – Chemical Biological Radiological Nuclear Defense (JPEO-CBRAND), the Assistant Secretary for Preparedness and Response (ASPR), and Biomedical Advanced Research and Development Authority (BARDA). All doses of mRNA-

> 1273 Vaccine referenced herein are 100 μg doses. All doses will be delivered in a multi-dose vial with a volume sufficient for 10 doses per vial. [. . .]
>
> C.1. **SCOPE.** The Department of Defense and Health and Human Services (HHS) require large scale manufacturing of vaccine doses in support of the national emergency response to the Coronavirus Disease 2019 (COVID-19) for the United States Government (USG) and the US population.
>
> C.1.1.1 Under Operation Warp Speed (OWS), the Department of Defense and HHS are leading a whole of nation effort to ensure development of promising vaccine, diagnostic and therapeutic candidates and ensure that these medical countermeasures are available in the quantities required to reduce SARS-CoV-2 transmission, identify prior and/or current infection, and improve patient care, thereby mitigating the impact of COVID-19 on the nation and its people. The DoD Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRD) is providing expertise and contracting support to HHS, in compliance with PL 115-92 Authorization Letter for DoD Medical Priorities, through an Interagency Agreement, signed April 23, 2020. As OWS products progress to clinical trials to evaluate the safety and efficacy of vaccines and therapeutics, it is critical that, in parallel, the USG supports large scale manufacturing so that vaccine doses or therapeutic treatment courses are immediately available for nationwide access as soon as a positive efficacy signal is obtained and the medical countermeasures are authorized for widespread use.

There is no genuine dispute that Moderna's activities related to the C-100 Contract are covered by 28 U.S.C. § 1498. Under this statute, "[w]henever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license," "the owner's remedy shall be by action against the United States in the United States Court of Federal Claims." 28 U.S.C. § 1498(a). To prevail on a § 1498 defense, a defendant must show (1) that it had "the authorization and consent of the Government" to engage in the allegedly infringing manufacture or use—which it is undisputed is expressly present in the C-100 contract—and (2) that such manufacture or use was "for the Government"—which the four corners of the C-100 Contract also make clear. *See Sevenson Env't Servs., Inc. v. Shaw Env't, Inc.*, 477 F.3d 1361, 1365 (Fed. Cir. 2007). As such, the unambiguous language of the C-100 Contract should be dispositive here.

But even if the Court were to look beyond the contract itself, after more than three years of litigation, Plaintiffs have failed to offer any evidence (nor could they) that Moderna's contract with the Government falls outside § 1498's ambit. Because Plaintiffs have not and cannot set forth any evidence raising a genuine dispute of material fact as to § 1498, this Court should grant summary judgment in Moderna's favor and dismiss Plaintiffs' claims against Moderna concerning COVID-19 vaccines provided by Moderna to the U.S. Government pursuant to the C-100 contract.

A. The Government Expressly Provided Authorization and Consent Through the C-100 Contract

The Government expressly authorized and consented to any allegedly infringing acts by Moderna in providing vaccine doses under the C-100 Contract. The C-100 Contract contains two broad Federal Acquisition Regulation ("FAR") clauses: 52.227-1 and 52.227-1, Alternate I. Ex. 1 (C-100 Contract) at 329. FAR 52.227-1, Alternate I, is the broader of the two and provides that "[t]he Government authorizes and consents to ***all*** use and manufacture of ***any*** invention described in and covered by a United States patent in the performance of this contract or any subcontract at any tier." 48 C.F.R. § 52.227-1, Alt. I. Nothing more is required for this Court to find authorization and consent under § 1498. 48 C.F.R. § 27.201-1(b) ("The Government may expressly authorize and consent to a contractor's use or manufacture of inventions covered by U.S. patents by inserting the clause at 52.227-1, Authorization and Consent.").

Plaintiffs have not seriously disputed that broad authorization language (like the two FAR clauses in Moderna's contract here) establishes authorization and consent as a matter of law—as courts have uniformly held. *See, e.g.*, *Saint-Gobain Ceramics & Plastics, Inc. v. II-VI Inc.*, 369 F. Supp. 3d 963, 980 (C.D. Cal. 2019) (holding incorporation of FAR 52.227-1 into contract constituted authorization and consent); *Carrier Corp. v. United States*, 534 F.2d 244, 247 n.4 (Ct. Cl. 1976) (noting that where a Government contract contains a broad authorization and consent

clause, the "alleged use need only be in the performance of the contract"); *BAE Sys. Info. & Elec. Sys. Integration Inc. v. Aeroflex Inc.*, 2011 WL 3474344, at *14–15 (D. Del. Aug. 2, 2011) (holding contract "contain[ed] an express consent and authorization" where it incorporated FAR 52.227-1, Alt. I); *Fiber Sys. Int'l, Inc. v. Applied Optical Sys., Inc.*, 2008 WL 906330, at *4 (E.D. Tex. Mar. 31, 2008) ("Consent is express when the Government contract contains an authorization and consent clause or incorporates the provision found in 48 C.F.R. § 52.227-1."); *Roberts v. Herbert Cooper Co.*, 236 F. Supp. 428, 430 (M.D. Pa. 1959) (holding that where a broad authorization and consent clause is included in a contract, "[n]o extended discussion is required on the question whether this action falls within the provisions of 28 U.S.C. § 1498 [because] Defendant's contracts are with the United States and the authorization and consent of the Government provided for in the statute is present").

Although the C-100 Contract clearly and unambiguously answers the question of authorization and consent, the Government also filed a Statement of Interest in this case explaining that "[t]he inclusion of FAR clauses 52.227-1 and 52.227-1, Alternate I in the [C-100] Contract constitutes the Government's express authorization and consent." D.I. 49 at 2; *cf. Auerbach v. Sverdrup Corp.*, 829 F.2d 175, 180 (Fed. Cir. 1987) (noting that for purposes of parallel copyright statute, "express documentary evidence" of the government's consent "[o]bviously . . . will do," and that "the form of the [Government's] consent" may include "retroactive consent"). Consistent with § 1498 jurisprudence, the Government further explained that "the effect of the Government's 'authorization and consent' is to relieve Moderna of any liability for patent infringement resulting in performance of the [C-100] Contract and to transfer to the United States any liability for the manufacture or use of the inventions claimed in the Patents-in-Suit resulting from the authorized and consented acts." D.I. 49 at 2. The Government's statement thus confirms what the C-100

Contract itself already makes plain and is an independent basis for finding authorization and consent.

B. Moderna's Manufacture and Sale of COVID-19 Vaccine Under the C-100 Contract Was "For" the Government

The "for the Government" prong of § 1498 is also not in genuine dispute. This prong is satisfied where "the use or manufacture of a patented method or apparatus occur pursuant to a contract with the government and for the benefit of the government." *Sevenson*, 477 F.3d at 1365; *see also Pieczenik v. United States*, 2023 WL 5031507, at *2 (Fed. Cir. Aug. 8, 2023) ("A government contractor's use is for the government's benefit when undertaken pursuant to a government contract that provides services the government sought."). Moreover, the government need not be the ***sole*** beneficiary. *Sevenson*, 477 F.3d at 1365–66; *Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis*, 583 F.3d 1371, 1378 (Fed. Cir. 2009). The U.S. Government procured doses of the COVID-19 vaccine from Moderna pursuant to a direct contract. Thus, there can be no genuine dispute that the procurement of those doses was for the Government's benefit, and there is again no need to look beyond the contract itself.

1. The Government Obtained a Benefit Simply by Procuring the Contracted-for Doses of COVID-19 Vaccine

Federal Circuit precedent guides the "for the Government" analysis under § 1498. Where, as here, the Government has contracted with a supplier and expressly authorized and consented to the allegedly infringing activity, "the inquiry [may be] reduced to the very simple question of whether the [accused infringers] establish that the government authorized or consented to the infringement, if such infringement in fact occurred." *Sevenson*, 477 F.3d at 1366 (cleaned up). "[W]here infringing activity has been performed by a government contractor pursuant to a

government contract and for the benefit of the government, courts have all but bypassed a separate inquiry into whether infringing activity was performed 'for the Government.'" *Id.*

Both Moderna and the Government agree that this truncated inquiry is appropriate here. *See* D.I. 49 at 9 ("[W]here the Government elects to include a contract provision expressly providing its authorization and consent, as it has done here, that decision is appropriately viewed as reflecting the Government's determination that the contract is for the Government's benefit."). ***First***, the undisputed evidence shows that the Government contracted with Moderna to "manufacture" the doses of the COVID-19 vaccine "for the United States Government." Ex. 1 (C-100 Contract) at 302. ***Second***, as explained in Section VI.A, the Government expressly authorized and consented to the allegedly infringing activity by including two broad FAR clauses in the C-100 Contract. *Id.* at 329. ***Third***, Moderna actually manufactured doses of the COVID-19 vaccine for the Government under the C-100 Contract, and the Government consequently "received the benefit of its contract, namely, procuring the vaccine that it then offered for free public distribution in an effort to thwart the COVID-19 pandemic." D.I. 49 at 10; SOF ¶¶ 14–35.

Unable to materially dispute each of these basic facts, Plaintiffs attack the § 1498 analysis endorsed by the Federal Circuit in *Sevenson*, suggesting that this Court need not follow it and instead find that the "for the Government" inquiry under § 1498 is a "factual dispute." D.I. 59 at 2. Plaintiffs cannot turn a question of statutory interpretation into a "factual dispute" by interpreting a statute contrary to Federal Circuit precedent. *See Madey v. Duke Univ.*, 307 F.3d 1351, 1359 (Fed. Cir. 2002) ("Federal Circuit law provides the applicable interpretation of § 1498(a). Section 1498(a) applies exclusively to patent law, meaning that Federal Circuit law applies."); *Deutsche Bank AG v. U.S.*, 742 F.3d 1378, 1381 (Fed. Cir. 2014) ("Statutory interpretation is a question of law."). Tellingly, Plaintiffs have not cited a single case examining

"benefit" as a factual matter where the contractor supplied the goods or services directly to the U.S. Government with the Government's express authorization and consent. Doing so here would contravene the many precedential cases holding the opposite at the summary judgment or motion to dismiss stages. *See, e.g.*, *Sevenson*, 477 F.3d at 1366 (holding that "the infringing method was practiced 'for the Government'" where "the government sought and received hazardous waste remediation services"); *Advanced Software*, 583 F.3d at 1376 (finding that "representations to this court that the accused activities are 'for the United States' and with its authorization and consent" reinforced applicability of § 1498); *IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1363 (Fed. Cir. 2014) ("We also note that the United States has unequivocally stated its position that suit under § 1498(a) is appropriate here. . . . Although the government's statement is not dispositive, it reinforces our conclusion that the United States has waived sovereign immunity in this case and, therefore, that IRIS's exclusive remedy is suit for recovery against the United States under § 1498(a).").

Plaintiffs' argument also conflicts with Congress's objectives in enacting § 1498. As the Supreme Court has explained, "[t]he purpose of [§ 1498] was to relieve the contractor entirely from liability of every kind for the infringement of patents in manufacturing anything for the government, and to limit the owner of the patent and his assigns and all claiming through or under him to suit against the United States in the Court of Claims." *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 343 (1928). The Federal Circuit has reaffirmed that "[t]he coverage of § 1498 [is] broad so as not to limit the Government's freedom in procurement by considerations of private patent infringement." *TVI Energy Corp. v. Blane*, 806 F.2d 1057, 1060 (Fed. Cir. 1986). In other words, § 1498 was enacted to give the Government broad freedom to contract with whomever it chooses to procure necessary goods or services while providing immunity to those

contractors. And it was designed to eliminate uncertainty for government contractors about whether they would face liability for fulfilling government contracts. *See Richmond Screw Anchor*, 275 U.S. at 345 ("The intention and purpose of Congress in the act of 1918 was to stimulate contractors to furnish what was needed for the war, without fear of becoming liable themselves for infringements to inventors or the owners or assignees of patents.").

Deferring to the Government's judgment regarding whether it received a benefit under § 1498 makes sense because policy decisions, including how to mount a response to crises like wars or pandemics, are generally left to the political branches rather than the judiciary. Engaging in a lengthy "factual dispute" over what is a benefit in every § 1498 case would impinge on the "Government's freedom in procurement" by causing contractors to become "fear[ful] of becoming liable themselves for infringements," even where the Government has expressly authorized and consented to any potential infringement. *TVI Energy*, 806 F.2d at 1060; *Richmond Screw Anchor*, 275 U.S. at 345. That is the exact result Congress sought to avoid. *See Zoltek Corp. v. United States*, 672 F.3d 1309, 1324 (Fed. Cir. 2012) ("the legislative purpose behind § 1498 is clear" and "survives today"). The Court need not and should not second-guess the Government's determination that it benefitted by procuring the contracted-for goods.

Plaintiffs also rely on *Larson v. United States*, where the Court of Federal Claims declined to apply § 1498 in the Medicare reimbursement context. 26 Cl. Ct. 365, 371 (1992). But *Larson* has no application here. To start, *Larson* did not involve a contract between the Government and the alleged infringer, and the Government expressly ***disputed*** that it had provided authorization and consent. *Id.* at 367–68. Instead, the case concerned providers who selected and purchased casts and splints from a supplier and later asked the Government for Medicare reimbursement. *Id.* Any "types, models, or brand names of casts and splints" could be reimbursed, and the Government

played no role in procuring them or in selecting which to use for any given patient. *See id.* at 367. In this context, the court concluded that "use of plaintiffs' casts and splints was for the benefit and convenience of the patient and provider, with no benefit to the government." *Id.* at 369.

Here, by contrast, the Government specifically and directly purchased and procured doses of Moderna's COVID-19 vaccine through the C-100 Contract and directed their distribution and use. SOF ¶¶ 14–35. The Government also provided its express authorization and consent in the C-100 Contract and reconfirmed through its Statement of Interest that it received a benefit by entering the C-100 Contract. Ex. 1 (C-100 Contract) at 329; D.I. 49. Although benefit is satisfied by the acceptance of goods under the contract, Moderna's COVID-19 vaccine, purchased by the Department of Defense to deploy a national mass vaccination effort, unlike the casts and splints in *Larson*, cannot be considered individual healthcare. Moderna's COVID-19 vaccine had effects far beyond individual recipients, including prevention of widespread severe infections of others across the nation and globally. SOF ¶¶ 38–41. That is clearly distinct from *Larson*.

Because it is undisputed that the Government procured the contracted-for COVID-19 vaccine doses and provided its express authorization and consent, this Court should hold as a matter of law that the "for the Government" prong of § 1498 is satisfied here.

2. Although the Court Need Not Consider "Benefit," the COVID-19 Vaccine Conferred Measurable Economic and Public Health Benefits on the Government

There is no need to go further to decide whether § 1498 bars Plaintiffs from accusing C-100 doses of infringement in this Court (it does). But, even if the Court were to decide that—despite the plain language of the contract and precedent to the contrary—it was appropriate to reassess whether the Government benefitted, there is still no genuine dispute that the provision of COVID-19 vaccine doses under the C-100 Contract was "for" the Government's benefit.

Moderna's expert witnesses, George Rutherford and Christopher Vellturo, analyzed years of data and academic literature and opined from epidemiologic, public health, and economic perspectives that the supplied doses of Moderna's COVID-19 vaccine significantly benefitted the Government by allowing it to robustly respond to an emergent public health crisis, suppress community transmission, and allow the nation's economy to recover. SOF ¶¶ 36–55; *see also Saint-Gobain*, 369 F. Supp. 3d at 977 ("A use is 'for the Government' if it is 'in furtherance and fulfillment of a stated Government policy' which serves the Government's interests and which is 'for the Government's benefit.'"). Plaintiffs do not dispute that these are real benefits. *See* Ex. 30-B (Rutherford Reply Rpt.) ¶¶ 9–13 (listing benefits Plaintiffs' experts do not dispute); Ex. 31-B (Vellturo Reply Rpt.) ¶ 17 (same). Plaintiffs instead argue these benefits are irrelevant because they are the product of "hindsight analysis that could not have been conducted at the time of infringement" and because they accrued to the public rather than the Government itself. Ex. 62 (Brill Rpt.) ¶¶ 17–22; Ex. 63 (Pitts Rpt.) ¶¶ 24–28. Neither of these arguments have merit.

First, as explained above, Plaintiffs have no support for their argument that some sort of "benefit" is required other than the one that was contracted for. Their assertion that any additional benefits that Moderna identified are irrelevant because they were not "quantified" at the time appears nowhere in § 1498. There is no reason to add an entirely new requirement to § 1498 that Congress did not see fit to include. Plaintiffs also have not identified any case law requiring the benefits of a contract—beyond the goods and services exchanged for consideration at the time of the agreement—to be quantifiable or even known at the time of contracting to satisfy the "for the Government" prong of § 1498. For good reason: such a requirement would be wholly unworkable. In *Sevenson*, for example, the Government contracted for remediation of hazardous waste at a Government site. 477 F.3d at 1363–64. Under Plaintiffs' argument, determining whether the

Government received some measurable benefit beyond the contract terms would have required the Government to conduct a multiyear environmental assessment of the effectiveness of the remediation to determine whether § 1498 even applied—before the contract was signed. Likewise, the Government may purchase military equipment like warships and weapons systems pursuant to § 1498. *See Zoltek*, 672 F.3d at 1312, 1315–17. But if Plaintiffs were right, military equipment could never be subject to § 1498 because it might not be used at all. That cannot be correct.

Second, Plaintiffs' argument that ***all*** benefits of the C-100 Contract purportedly accrued to members of the public rather than the Government does not create a material factual dispute.[6] Plaintiffs appear to agree that Moderna's COVID-19 vaccine afforded significant benefits to the individuals who received the vaccine, resulted in wider population-level health benefits as a result of reduced transmission and saved the Government billions of dollars. *E.g.*, Ex. 62 (Brill Rpt.) ¶¶ 17–22 (agreeing that "COVID-19 vaccines had significant benefits to the individuals who received them, as well as to the American public more generally"); Ex. 63 (Pitts Rpt.) ¶¶ 24–28 (agreeing that "things like the effectiveness of the vaccine, the infections avoided, the lives saved, and the growth of the overall economy" are "benefits" to "American public in general"). Plaintiffs only dispute whether these benefits should be considered benefits "for the Government" as a matter of policy. But Plaintiffs' subjective opinions as to what constitutes good policy or what policy decisions the Government should make are irrelevant to the § 1498 inquiry. Congress did not put limits on what benefits count, and the Court should not make policy judgments reserved for Congress. *See RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 649 (2012).

[6] Plaintiffs attempt to bolster their argument with expert testimony from Alex Brill and Peter Pitts. That testimony does not pass muster under *Daubert* and should not be considered here, for the reasons explained in Moderna's concurrently filed motion to exclude the testimony of Messrs. Brill and Pitts (filed pursuant to the Scheduling Order, D.I. 485).

C. The Undisputed Evidence Confirms Which Doses Were Made and Sold Pursuant to the C-100 Contract and Should Be Dismissed from the Case

Discovery has confirmed which doses of Moderna's COVID-19 vaccine must be dismissed from the case under § 1498. Moderna manufactured and sold to the U.S. Government for its use 500,001,540 doses of COVID-19 vaccine under the C-100 Contract. SOF ¶ 32. The U.S. Government procured those doses through the original C-100 Contract and several amendments, which were all paid for and accepted by the U.S. Government. SOF ¶¶ 32–35. Plaintiffs have not raised any evidence or argument disputing that these doses were manufactured for and sold to the Government under the C-100 Contract. Accordingly, those 500,001,540 doses should be dismissed from the case.

* * *

Moderna's provision of COVID-19 vaccine doses under the C-100 Contract was for the Government and with its authorization and consent. Accordingly, § 1498 applies, and Moderna is not liable for any alleged infringement of the Patents-in-Suit for those C-100 doses. Plaintiffs' sole remedy, if any, lies in an action against the Government in the Court of Federal Claims.

VII. PLAINTIFFS' DOE THEORIES ARE BARRED BY PROSECUTION HISTORY ESTOPPEL

"Broad application of [DOE] 'conflicts with the definitional and public-notice functions of the statutory claiming requirement.'" *MED-El Elektromedizinische Gerate GmbH v. Advanced Bionics, LLC*, 657 F. Supp. 3d 604, 615 (D. Del. 2025) (quoting *Eli Lilly and Co. v. Hospira, Inc.*, 933 F.3d 1320, 1330 (Fed. Cir. 2019)). "Unchecked, the doctrine may take on a life of its own, unbounded by the patent claims. Therefore, courts developed doctrines to limit a patentee's ability to assert infringement under the doctrine of equivalents." *Id.* (cleaned up). One such doctrine is prosecution history estoppel, which "can occur in two ways: either (1) by making a narrowing amendment to the claim ('amendment-based estoppel') or (2) by surrendering claim scope through

argument to the patent examiner ('argument-based estoppel')." *Amgen Inc. v. Coherus BioSciences Inc.*, 931 F.3d 1154, 1159 (Fed. Cir. 2019). "Whether prosecution history estoppel applies . . . is ***a question of law*** . . . ." *Id.*; *see also Jang v. Boston Sci. Corp.*, 872 F.3d 1275, 1288 (Fed. Cir. 2017). Both forms of estoppel apply here and bar Plaintiffs' DOE theories as a matter of law.

A. Amendment-Based Estoppel Bars Plaintiffs' DOE Theories

"When the patentee responds to [a PTO] rejection by narrowing his claims, . . . prosecution history estops him from later arguing that the subject matter covered by the original, broader claim was nothing more than an equivalent. Competitors may rely on the estoppel to ensure that their own devices will not be found to infringe by equivalence." *Festo*, 535 U.S. at 727. "[T]he . . . rule is to place the burden on the patent holder to establish the reason for an amendment required during patent prosecution." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 33 (1997). "Where no explanation is established, however, the court should presume that the patent applicant had a substantial reason related to patentability for including the limiting element added by amendment. In those circumstances, prosecution history estoppel would bar the application of the doctrine of equivalents as to that element." *Id.*

1. Plaintiffs Undisputedly Narrowed the Claimed Lipid Ranges to Overcome the Prior Art during Prosecution and Surrendered All Territory Between the Original and Amended Claim Ranges.

The asserted Ratio Patents claim priority to the '069 patent, which Plaintiffs recently dropped from the case. The prosecution of the '069 patent is important to understand why prosecution history estoppel applies here because it is the first patent where Plaintiffs narrowed the claimed ranges. SOF ¶¶ 56–81. The original claims of the application that led to the '069 patent included mol % ranges of the four lipid components that were preceded by the word "about." *See*

SOF ¶¶ 58.[7] But the Examiner rejected those claims as anticipated and/or obvious in view of the prior-art reference MacLachlan. MacLachlan (Ex. 57) is an earlier patent application publication by the inventor of the '069 patent and the Ratio Patents, and the Examiner recognized that the inventor was trying to claim what he had already disclosed. MacLachlan taught the same lipid components "with ranges . . . amounts that overlap with the instantly claimed ranges." SOF ¶¶ 60–62; Ex. 73 (July 30, 2010 – '069 PH) at 5; Ex. 74 (May 12, 2011 – '069 PH) at 2–4. The Examiner was concerned that "the relative amounts of components read on a broad range of amounts because of the term 'comprising about'. The applicants do not provide a definition of the term in the specification. Thus, 'comprising about' could embrace an amount +/- 10, 20, 30 mol % of a lipid component." SOF ¶ 67; Ex. 74 (May 12, 2011 – '069 PH) at 2. In other words, the Examiner understood that the claimed ranges could extend from, for example, 20 to 95 mol % cationic lipid instead of the claimed 50 to 60 mol %.

To get around their own inventor's publication in these rejections, Plaintiffs deleted "about" from the mol % range limitations such that the "***amended [claims] recite[] narrow ranges*** for each of the lipid components." SOF ¶ 76; Ex. 75 (Aug. 11, 2011 – '069 PH) at 8; *see also id.* at 4 (removing "about" from the mol % range limitations); Ex. 41 (2024-02-08 *Markman* Tr.) at 36:17–25 (Plaintiffs agreeing that the removal of "about" narrowed the pending claims). Plaintiffs did the same during the prosecution of the '359 and '435 patents. SOF ¶¶ 80–81; Ex. 77 (Mar. 28, 2012 – '359 PH) at 4 (cancelling claim 1 with "about" and adding claim 47 that recited cationic lipid and conjugated lipid mol % ranges without "about"); Ex. 79 (Feb. 26, 2015 – '435 PH) at 2 (cancelling claim 1 with "about" and adding claim 47 that recited cationic lipid, non-cationic lipid,

[7] While the '069 Patent is no longer asserted in this case, its prosecution history is critical to the undisputed narrowing of the mol % range limitations in all claims of the Ratio Patents. *See* SOF ¶¶ 56–81.

and conjugated lipid mol % ranges without "about"); D.I. 266 at 20–22. After making these amendments, the Examiner withdrew his rejection based on the prior-art reference MacLachlan, and the patents issued. SOF ¶ 104. By the time the '378 Patent was filed, the patentee no longer even bothered to include "about" in the claims of the application.

This is ***undisputedly a narrowing amendment***. *See, e.g.*, *Eli Lilly*, 933 F.3d at 1330; *San Rocco Therapeutics, LLC v. Bluebird Bio, Inc.*, 2025 WL 1425341, at *5 (D. Del. May 16, 2025). Using the '069 Patent as an example, the chart below compares the originally claimed ranges (applying +/-30% to the ranges, consistent with the scope of "about"), and the amended claimed ranges (with the variability permitted by rounding, as construed by the Court):

Lipid Component[8]	**Original Claim 1, '069 Patent (with "about")**	**Amended Claim 1, '069 Patent (without "about")**
Cationic Lipid	20 – 95 mol %	49.5 – 65.49 mol %
Phospholipid (non-cationic lipid)	0 – 40 mol %	3.5 – 10.49 mol %
Cholesterol (non-cationic lipid)	0 – 70 mol %	29.5 – 40.49 mol %
Conjugated Lipid	0 – 32 mol %	0.45 – 2.49 mol %

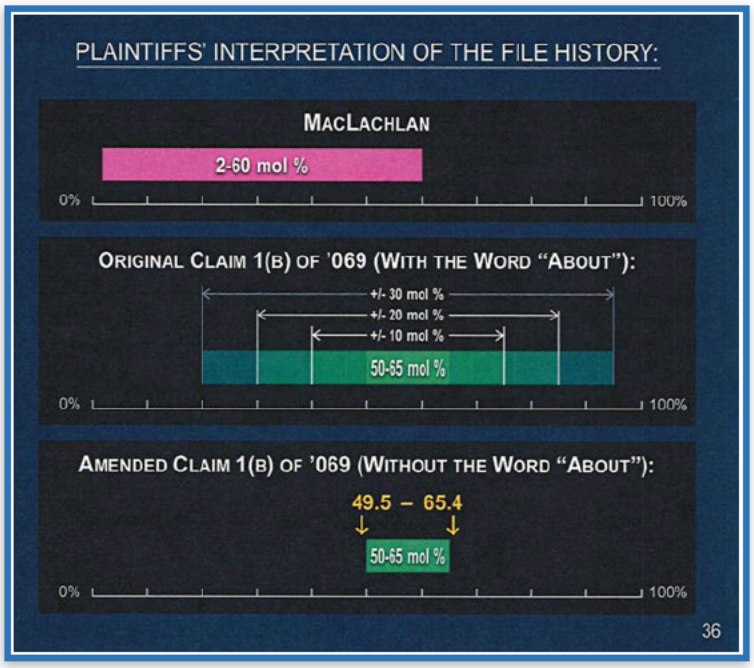
During *Markman*, the Court recognized this as a narrowing amendment, finding that "[w]hen Plaintiff removed the phrase 'comprising about,' it . . . ***clearly disclaimed*** these broader ranges . . . ." SOF ¶¶ 82–84; D.I. 266 at 21 (where the broader ranges are "+/- 10, 20, 30 mol %"); *see also id.* at 22. Plaintiffs' *Markman* presentation admitted to the disclaimer, too, providing ample support for the Court's conclusion that Plaintiffs admitted that "during prosecution, they …

[8] Some Ratio Patent claims separately recite "phospholipid" and "cholesterol" ranges; other claims group them together as a "non-cationic lipid" that can be comprised of two or more lipids (*i.e.*, when the "non-cationic lipid" limitation is used, the "phospholipid" and "cholesterol" component would be added up to find the total amount of "non-cationic lipid" claimed). Plaintiffs' DOE theories regarding the "non-cationic lipid" limitation, however, only implicate the '435 patent, which recites a single limitation reciting the mol % range for the "non-cationic lipid" limitation. The other Ratio Patents, including the'069 patent that is used as the primary example for why and how prosecution history estoppel applies in this case, recites the limitations separately.

disclaimed the broader variability that was encompassed by the term 'about.'"[9] D.I. 266 at 21; Ex. 41 (2024-02-08 *Markman* Tr.) at 35:16–44:5. Moderna's motion is based on that admitted disclaimer, which applies with equal force to all asserted Ratio Patents. *See Elkay Mfg. Co. v. Ebco Mfg. Co.,* 192 F.3d 973, 980 (Fed. Cir. 1999) ("When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation."); *Regents of Univ. of Minn. v. AGA Med. Corp.*, 717 F.3d 929, 943 (Fed. Cir. 2013).

Specifically, Plaintiffs agreed that "about" in the original Ratio Patent claims comprised "+/- 10, 20, 30 mol %" as defined by the Examiner during prosecution. *E.g.*, SOF ¶¶ 67, 101–103, 107; D.I. 170 at 14, 37–38; Ex. 41 (*Markman* Tr.) at 36–37; *see also* Ex. 43 (Plaintiffs' *Markman* Demonstratives) at 32, 36. Plaintiffs also confirmed that "the Examiner said, that 'about' could mean plus-or-minus 10, 20, or 30 [percent]," that then-pending claim "ha[d] a very broad range, similar to [MacLachlan]," that "you get rid of 'about' and you narrow [the claim]," and that means "you get rid of that plus-or minus 10, 20, 30 [percent]." Ex. 41 (*Markman* Tr.) at 42:9–17. Plaintiffs' *Markman* demonstrative, reproduced in part below, shows the scope of "original claim 1(b)" with "about" and the scope of "amended claim 1(b)" without "about" (Ex. 43 at 36):

[9] The Court ultimately construed the claims to permit rounding. D.I. 266. Although Moderna disagrees with that construction, its argument here is based only on disclaimer of amounts *outside* the rounded amounts permitted by the Court's construction.



Thus, under "Plaintiffs' interpretation of the file history," original claim 1(b) (with "about") included particles with, for example, 20 to 95 mol % cationic lipid but the amended claim (without "about") only covered particles with 49.5 to 65.4 mol % cationic lipid—i.e., the claimed range 50 to 65 mol % plus the variation permitted by the court for rounding (summarized in the chart in above). *Id.* In doing so, Applicants surrendered from 20 to 49.49 mol % cationic lipid—i.e., the surrendered territory. *Festo*, 535 U.S. at 740 ("A patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim."); *see also San Rocco*, 2025 WL 1425341 at *3 ("When a patent applicant narrows the claims during prosecution in response to a rejection, the subject matter between the original claim and the amended claim cannot later be re-captured by the doctrine of equivalents."). Plaintiffs' disclaimer applies equally to all three or four lipid mol % range limitations in the Ratio Patents that were narrowed by deleting "about." SOF ¶¶ 101–116. Accordingly, there is no dispute that the portion of the claimed ranges previously encompassed by "about" is the surrendered territory. SOF ¶¶ 85–116.

2. Because Plaintiffs' DOE Theories Are Based Solely on Lipid Mol % in the Surrendered Territory, They Fail as a Matter of Law

It is black letter law that "[w]hen the patentee has chosen to narrow a claim, courts may presume . . . that the territory surrendered is not an equivalent of the territory claimed." *Festo*, 535 U.S. at 741. Plaintiffs recognized these principles applied at *Markman* and confirmed that to show infringement, they "would need to show . . . that Moderna's product . . . has particles between 49.5 and 65.49 mol percent cationic lipid" based on the removal of "about" from in the amended claims. Ex. 41 (2024-02-08 *Markman* Tr.) at 39:22–40:9 (using claim 1 of the '069 patent as an example). Yet Plaintiffs' DOE theories for the cationic, non-cationic, and conjugated lipid mol % range limitations are each based on an alleged equivalent outside of the claimed mol % range but within the territory surrendered during prosecution. SOF ¶¶ 85–100. The table below shows the original claims of the '435 patent compared to each component's alleged equivalent and the prior-art reference MacLachlan.

Lipid Component	Issued Claims (with Rounding)	Plaintiffs' Alleged Equivalent	Surrendered Territory	Prior Art MacLachlan
Cationic Lipid	49.5 – 85.49 mol %	44.5 – 49.49 mol %	20 – 49.499 and 85.5 – 95 mol %	2 – 60 mol %
Non-Cationic Lipid	12.5 – 49.549 mol %	49.55 – 53.5 mol %	0 – 12.499 and 49.55 – 79.5 mol %	25 – 100 mol %
Conjugated Lipid	0.45 – 2.49 mol %	2.5 – 3.5 mol %	0 – 0.449 and 2.5 –32 mol %	1–20 mol %

Plaintiffs' DOE arguments are therefore barred by prosecution history estoppel. *See* SOF ¶¶ 106–16.

This case is no different than *San Rocco Therapeutics v. Bluebird Bio*. There, plaintiffs argued that "a 3.2-kb nucleotide fragment" was equivalent to "a 2.7 kB nucleotide fragment." 2025 WL 1425341, at *3. The plaintiffs, however, had amended their claim during prosecution, changing "large portions of the β-globlin locus control region" to "3.2-kb nucleotide fragment."

Id. at *3–4. Because the amended claim recited "a specific number" and because the plaintiffs' purported equivalent of 2.7 kB was within the territory of the original claims (i.e., "large portions"), the alleged equivalent was disclaimed. *See id.* at *5. Here, the amended claims recite "a specific number" and the alleged equivalents are within the surrendered territory (what was covered by "about"). Thus, the alleged equivalents were disclaimed.

Plaintiffs' only response to these undisputed facts is to claim that the amendment only bears a "tangential relationship" to the equivalent in question. That argument cannot be squared with the law or the undisputed facts. A "tangential" amendment is one where "the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent." *Insituform Techs., Inc. v. CAT Contr., Inc.*, 385 F.3d 1360, 1370 (Fed. Cir. 2004) (cleaned up). That plainly does not apply here because Plaintiffs amended the ranges of claimed lipid components to overcome the prior art, and they are now accusing the very ranges of lipid components that they excluded from their claims. *See* § VII.A.1, *supra*. As seen above, the scope Plaintiffs seek to capture through DOE is both within the surrendered territory and the prior art MacLachlan that they sought to overcome, confirming the tangential exception does not apply. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 344 F.3d 1359, 1369 (Fed. Cir. 2003) ("[A]n amendment made to avoid prior art that contains the equivalent in question is not tangential; it is central to allowance of the claim."). Because "both the reason for the amendment and the asserted equivalent relate to the concentration of the [lipid components]," Plaintiff cannot "show[] that the rationale underlying the amendment was merely tangential to the accused equivalent." *Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1306 (Fed. Cir. 2005).

Moreover, Plaintiffs made clear during prosecution that the mol % range limitations were essential to their alleged invention. Like in *Biagro*, where "both the reason for the amendment and

the asserted equivalent relate to the concentration of the [lipid components]," the tangential exception does not apply. 423 F.3d at 1306; *see also San Rocco*, 2025 WL 1425341, at *5 (concluding that the tangential exception did not apply where the applicant's remarks accompanying the claim amendment explained that the larger claim scope had been relinquished and the narrower amended scope was tied to the alleged point of novelty). Plaintiffs repeatedly stated that their claimed invention was the 1:57 SNALP formulation (i.e., a formulation with 57 mol % cationic lipid) which had "new and unexpected results." SOF ¶¶ 63–65, 77–78; Ex. 72 (Jan. 31, 2011 – '069 PH) at 8; *see also id.* ("1:57 SNALP formulations advantageously impart ***increased activity*** of the encapsulated nucleic acid . . . and ***improved tolerability***" (emphasis in original)); *id.* at 5 ("***more efficacious***" (emphasis in original)); Ex. 75 (Aug. 11, 2011 – '069 PH) at 9–10 (repeating same arguments). Plaintiffs also admitted that they "distinguish[ed] the prior art" in the prosecution of the '069 patent based on "the concentration of cationic lipid, among other elements." D.I. 170 at 51. Having relied on the mol % range limitations as a point of novelty, Plaintiffs cannot now allege those ratios are merely tangential.

B. Argument-Based Estoppel Bars Plaintiffs' Alleged Cationic Lipid Equivalents

In addition to amendment-based estoppel, Plaintiffs' alleged equivalents to the "cationic lipid" limitation in the '359 and '435 Ratio Patents are barred by prosecution history estoppel for another reason: Plaintiffs clearly and unmistakably surrendered all equivalents of a claimed formulation with ***less than*** 50 mol % cationic lipid. "To invoke argument-based estoppel, the prosecution history must evince a 'clear and unmistakable surrender of subject matter.'" *Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., Inc.*, 347 F.3d 1314, 1326 (Fed. Cir. 2003). "[T]he relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter," when assessing whether there were "clear assertions." *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1368 (Fed. Cir. 2007).

During prosecution, Plaintiffs clearly and unmistakably tied their claimed invention to formulations with high concentrations of cationic lipid—specifically to a formulation with 57 mol % cationic lipid. For example, Plaintiffs argued that "[i]t is clear from the specification that the present invention is based, in part, on the surprising discovery that 1:57 SNALP formulations provide ***new and unexpected*** results." SOF ¶¶ 63–65, 77–78; Ex. 72 (Jan. 31, 2011 – '069 PH) at 8 (emphasis in original); *see also id.* ("[T]he presently claimed 1:57 SNALP formulations advantageously impart ***increased activity*** of the encapsulated nucleic acid (e.g., an interfering RNA such as siRNA) and ***improved tolerability*** of the formulations . . . ." (emphasis in original)); *id.* at 10 ("significantly ***more efficacious***" (emphasis in original)); *id.* ("substantially ***more effective***" (emphasis in original)); *id.* ("Examples provided in the specification demonstrate that the presence of increased amounts of cationic lipids results in improved and/or enhanced activity of the presently claimed 1:57 SNALP formulations."); Ex. 75 (Aug. 11, 2011 – '069 PH) at 9–10 (emphasis in original) ("SNALP formulations having increased amounts of cationic lipid, e.g. one or more cationic lipids comprising from 50 mol % to 65 mol % of the total lipid present in the particle, provide ***unexpectedly superior advantages***." (emphasis in original)). In fact, Plaintiffs agreed that they "distinguish[ed] the prior art based on the concentration of cationic lipid," D.I. 170 at 51, and admitted that "***[i]t is clear*** . . . the present invention is based, in part, on the surprising discovery that 1:57 SNALP formulations provide ***new and unexpected results***," Ex. 72 (Jan. 31, 2011 – '069 PH) at 9 (second emphasis in original). *See Amgen*, 931 F.3d at 1159–60 ("[C]lear assertions made during prosecution in support of patentability, whether or not actually required to secure allowance of the claim" are also supportive of estoppel).

Despite these assertions, and others, that ***higher*** concentrations of cationic lipid are "superior" and that the claims were directed to formulations with 57 mol % cationic lipid, Plaintiffs

now seek to accuse products with ***less*** than 50 mol % cationic lipid. But Plaintiffs "made th[e] point repeatedly" that increased amounts of cationic lipids were "superior," "more efficacious," and "more effective"—all while speaking about a formulation with 57 mol % cationic lipid. *See San Rocco*, 2025 WL 1425341, at *7. "[T]he repetition makes the surrender indisputable." *Id.* Indeed, Plaintiffs continued to repeat these statements during the related IPR proceedings. *E.g.*, Ex. 64 ('435 Appeal, D.I. 67) at 19 ("The '435 patent is directed to ***the surprising discovery*** that nucleic acid-lipid particles with ***high levels of cationic lipids*** . . ."); Ex. 65 ('069 IPR, Paper 15) at 7; Ex. 66 ('069 IPR, Ex. 2004) at 71; Ex. 67 ('435 IPR, Paper 24) at 35 (distinguishing prior art because "neither reference teaches or suggests ***increasing the cationic lipid content above 50 mol %***"); *see also Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1361 (Fed. Cir. 2017) ("Because an IPR proceeding involves reexamination of an earlier administrative grant of a patent, it follows that statements made by a patent owner during an IPR proceeding can be . . . relied upon to support a finding of prosecution disclaimer.").

These statements leave no doubt that Plaintiffs disclaimed any formulations with less than 50 mol % cationic lipid. Yet Plaintiffs accuse exactly that—i.e., Moderna's accused formulations with less the 50 mol % cationic lipid. Plaintiffs' repeated statements that the claims are directed to formulations with 57 mol % cationic lipid "makes the surrender indisputable." *San Rocco*, 2025 WL 1425341, at *7. Thus, Plaintiffs' DOE theory for the '359 and '435 Ratio Patents directed at formulations with less than 50 mol % cationic lipid is barred by prosecution history estoppel.

VIII. THE ASSERTED '651 PATENT CLAIMS ARE INVALID FOR INDEFINITENESS

The Court should grant summary judgment that the asserted claims of the '651 patent are indefinite. A patent must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112 ¶ 2 (pre-AIA). The claims of the '651 patent, however, "fail to inform, with reasonable certainty, those

skilled in art" what the boundary is between "fully" and "partially" encapsulated mRNA. *Nautilus*, 572 U.S. at 901.

The patent identifies three states of encapsulation for a nucleic acid with respect to a lipid vesicle—fully encapsulated, partially encapsulated, and not encapsulated. D.I. 266 at 32–37; SOF ¶¶ 117–121. The '651 patent only claims lipid vesicles with specified percentages of mRNA in ***one*** state—i.e., vesicles wherein the mRNA is "fully encapsulated". But the patent does not teach or identify any technique to use to determine whether a lipid vesicle formulation has the required percentages of "fully encapsulated" mRNA. Moreover, the undisputed evidence in this case shows that although there are potentially multiple ways to measure the "encapsulation" of mRNA generally, there is no test to distinguish between these two states. In addition, the methods that measure "encapsulation" generally lead to materially different results. Either of these flaws is enough to hold the '651 patent claims indefinite as a matter of law. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015) (indefiniteness is a question of law); *see also Halliburton Energy Servs., Inc. v. M–I LLC*, 514 F.3d 1244, 1246 (Fed. Cir. 2008) (affirming grant of summary judgment that claims were indefinite).

A. The Term "fully, as distinct from partially" Lacks Meaningfully Precise Scope

A person of skill in the art would have no reasonable certainty of the scope of claim 1 of the '651 patent, which recites: "A lipid vesicle formulation comprising: . . . messenger RNA (mRNA), ***wherein at least 70% of the mRNA in the formulation is fully encapsulated in the lipid vesicles***." SOF ¶¶ 117. Claims 13 and 14 depend from claim 1, and respectively require at least 80% and 90% of the mRNA be "fully encapsulated." Ex. 1 ('651 patent) cls. 1, 13, 14. Here, the Court construed "fully encapsulated" in these limitations to mean "fully, as distinct from partially, contained inside the lipid vesicles." D.I. 266 at 32–37; D.I. 267. Thus, the claims require that a certain percentage of mRNA be fully—not partially—encapsulated. The problem, however, is that

"[e]ven if a claim term's definition can be reduced to words, the claim is still indefinite if a person of ordinary skill in the art cannot translate the definition into meaningfully precise claim scope." *Halliburton*, 514 F.3d at 1251. That is undisputedly the case for the term "fully, as distinct from partially"—i.e., while the construction is supported by the patent specification, the term cannot be translated into a meaningfully precise scope.

First, the patent provides no guidance as to the difference between "fully" and "partially" encapsulated. It merely acknowledges that both states of encapsulation are possible—either the mRNA is "fully" encapsulated, or it is "partially" encapsulated. The specification references "full" and "partial" encapsulation once, stating "lipid encapsulated can refer to a lipid formulation which provides a compound[, e.g., the mRNA,] with full encapsulation, partial encapsulation, or both." Ex. 1 ('651 patent) at 5:38–40. And "fully" and "partially" are undefined in the prosecution history. Thus, the '651 patent "fails to provide guidance to a skilled artisan for how to measure the newly coined characteristic ['partially encapsulated'] with reasonable certainty." *Pac. Coast Bldg. Prods., Inc. v. CertainTeed Gypsum, Inc.*, 816 F. App'x 454, 459 (Fed. Cir. 2020).

Second, there is no accepted definition in the field for "fully" or "partially" encapsulated. With respect to "fully encapsulated," Moderna's experts offered unrebutted testimony that "fully encapsulated" had no defined meaning. *See also* SOF ¶¶ 131–32; Ex. 56 (Prud'homme Dep. Tr.) at 180:21–181:21 (testifying that there is "no real definition of fully encapsulated or how to measure it or what that term means"). Plaintiffs' validity expert's definition for "fully encapsulated" simply repeats the claim construction. SOF ¶ 130; Ex. 55 (Murthy Reb. Rep.) ¶ 501. Similarly, with respect to "partially" encapsulated, Moderna's experts offered unrebutted testimony that the term has no definition. For example, Dr. Robert Prud'homme testified that "[t]here is no accepted definition in the field as to what 'partially' encapsulated means," and

"'partial' is also unclear as to its explicit definition and certainly unclear on whether one could measure it or not." SOF ¶ 131; Ex. 56 (Prud'homme Dep. Tr.) at 180:21–181:21; Ex. 58 (Meulien Dep. Tr.) at 43:17–44:3 (testifying that he did not know the difference between "fully encapsulated" and "partially" encapsulated" nucleic acid and that he was not sure what either term meant). Plaintiffs' scientists, who worked on lipid-encapsulated nucleic acids, also could not define "partially encapsulated" or how to measure the percentage of "partially encapsulated" mRNA. For example, Genevant scientist Stephen Reid testified that "partially encapsulated" was not a term "typically" used in their work, "could mean different things," and was "vague." SOF ¶ 125; Ex. 50 (Reid Dep. Tr.) at 58:3–7. Former scientist for Plaintiffs Adam Judge testified that he did not know what "partially encapsulated" meant and did not know a way to test for it. SOF ¶ 124; Ex. 49 (Judge Dep. Tr.) at 47:11–12. Nor could Plaintiffs' experimental testing expert provide a definition of "partially encapsulated." SOF ¶ 128; Ex. 53 (Schuster Dep. Tr.) at 169:8–20.

Plaintiffs' other scientists and experts offered inconsistent explanations for "partially encapsulated." SOF ¶¶ 122–137. Far from creating a fact question, this ***confirms*** the claims are indefinite. *See Teva*, 789 F.3d at 1345; *Infinity Computer Prods., Inc. v. Oki Data Ams., Inc.*, 2019 WL 2422597, at *5 (D. Del. June 10, 2019). For example, Lloyd Jeffs, named '651 patent inventor, testified that in "some contexts" "the partial in partial encapsulation refer to a portion of the nucleic acid that is not encapsulated," SOF ¶ 123; Ex. 48 (Jeffs Dep. Tr.) at 81:5–8, and another inventor, Ian MacLachlan testified that "partially encapsulated" included "material that is on the outside or on the surface of a lipid vesicle," SOF ¶ 122; Ex. 47 (MacLachlan Dep. Tr.) at 30:10–19. In contrast, Plaintiffs' expert, Dr. Thompson, disagreed that nucleic acid on the surface is "partially encapsulated." SOF ¶ 129; Ex. 54 (Thompson Dep. Tr.) at 136:13–15. As such, there is no

consensus on whether "partially encapsulated" nucleic acid would include nucleic acid that is on the outside surface of a lipid particle or vesicle. The inconsistency in the definitions could result in different ways of someone calculating the percentage of "fully encapsulated" mRNA; this is particularly true where at least five experts and scientists (both Moderna's and Plaintiffs') could not identify what "partially encapsulated" means or how to draw a line between "partially" and "fully encapsulated." "A claim is indefinite if its language 'might mean several different things and no informed and confident choice is available among the contending definitions.'" *Media Rights Techs., Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1371 (Fed Cir. 2015).

Third, Plaintiffs have identified no testing methods that differentiate between "fully" and "partially" encapsulated. Plaintiffs offer a single test that only measures "encapsulation" generally—not whether that encapsulation is partial or full. SOF ¶ 126; Ex. 51 (Jeng Dep. Tr.) at 64:15–22 (testifying that in his "technical view," he did not distinguish "encapsulation or fully encapsulation"). And no one identified a test to measure the percentage of "partially" encapsulated nucleic acid. *See* SOF ¶¶ 124, 135–37; Ex. 49 (Judge Dep. Tr.) at 48:23–49:2 ("Can you think of any way that you would be able to test for partial encapsulation of nucleic acid? A. That's -- I don't -- I -- I don't know."); Ex. 59 (Murthy Dep. Tr.) 124:4–125:21 (unable to name any analytical technique to measure the percentage of "partially encapsulated" nucleic acid). Without a test to identify the "objective bounds" of "fully" and "partially" encapsulated, Plaintiffs' testing may inaccurately count "partially" encapsulated mRNA as "fully encapsulated" mRNA, leading to an incorrect conclusion on infringement. That runs afoul of § 112 ¶ 2 requirements. *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002) (citation omitted) ("The primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the

patent, so that interested members of the public, e.g., competitors of the patent owner, can determine whether or not they infringe."); *see also SmithKline Beecham Corp. v. Apotex Corp*., 403 F.3d 1331, 1340-41 (Fed. Cir. 2005); *Halliburton*, 514 F.3d at 1251.

B. Available Methods of Measuring "encapsulation" at the Alleged Priority Date of the '651 Patent Give Materially Different Results.

Setting aside the ambiguity of "fully" versus "partially," the lack of disclosure as to how to quantify the "at least 70% / at least 80% / about 90%" "encapsulated" mRNA generally (i.e., before even attempting to ascertain if it is "fully" or "partially" encapsulated) also renders the asserted claims of the '651 patent indefinite. Ex. 1 ('651 patent) cls. 1, 13, 14. *First*, during claim construction, the Court found that the claims required measuring the percentage of mRNA "fully encapsulated," not (as Plaintiffs argued) measuring encapsulation efficiency. D.I. 266 at 36–37. It is undisputed that no one has identified a test to measure the percentage of mRNA "fully encapsulated." As such, under the Court's claim construction, there is no method of measuring available to assess whether an accused product falls within the scope of the claim, and the claim is indefinite. *Teva*, 789 F.3d at 1341.

Second, despite the Court's ruling on this issue, Plaintiffs continue to rely on methods of "encapsulation efficiency" to satisfy the measurement required by the claim limitations. SOF ¶ 137; Ex. 55 (Murthy Reb. Rep.) ¶ 107. Even assuming the Court's ruling on this should be reconsidered (it should not), the '651 patent claims are still indefinite because "(1) different known methods exist for calculating a claimed parameter, (2) nothing in the record suggests using one method in particular, and (3) application of the different methods result in materially different outcomes for the claim's scope such that a product or method may infringe the claim under one method but not infringe when employing another method." *Ball Metal Beverage Container Corp. v. Crown Packaging Tech., Inc.*, 838 F. App'x 538, 542 (Fed. Cir. 2020); *see also Dow Chem. Co.*

v. Nova Chems. Corp. (Canada), 803 F.3d 620, 634 (Fed. Cir. 2015); *Teva*, 789 F.3d at 1344–45. At the alleged priority date of the '651 patent, it is undisputed there were at least seven known tests to measure "encapsulation efficiency." *See, e.g.*, SOF ¶¶ 138–39, 143. The '651 Patent does not mention a single method to measure encapsulation of nucleic acids in lipid vesicles. Although Plaintiffs' expert Dr. Murthy claims a person of skill in the art would have known to use a dye-exclusion assay, neither the claims nor the specification provides any indication that this particular test must be used to measure the claimed 70 % / 80 % / 90 % "fully encapsulation." *Dow Chem.*, 803 F.3d at 634 ("Neither the patent claims nor the specification . . . provide[] any guidance as to which method."). In fact, that dye-exclusion test only "measures" encapsulation indirectly: it quantifies the free (non-vesicle-associated) nucleic acid, subtracts that quantified amount from the total nucleic acid added, and then treats the remainder as "encapsulated" (i.e., the % encapsulated is a calculated figure). In other words, the test simply reports how much nucleic acid is ***not*** encapsulated; it does not (and cannot) distinguish between states of encapsulation.

The lack of disclosure in the '651 patent is particularly problematic because the Blenke reference demonstrated that the seven tests for measuring encapsulation efficiency could lead to "materially different results." *Ball Metal*, 838 F. App'x at 542; *see also Dow Chem.*, 803 F.3d at 634; *Teva*, 789 F.3d at 1344–45. SOF ¶ 140–41; Ex. 60 (Blenke) at 796 Table 2. For example, Figure 4 of Blenke illustrates that depending on the test used, the percentage of nucleic acid encapsulated may be as high as 75 % or as low as 50 %—i.e., the difference between falling within the scope of claim 1 or not. SOF ¶ 142; Ex. 60 (Blenke) at 796 Figure 4 (using sample 4 in the chart as an example); *see also* SOF ¶ 144; Ex. 61-A (Prud'Homme Op. Rep.) ¶ 136. Other experimental results show that encapsulation measurements could range from 11% to 50%—i.e., a 40 % variability in the testing results. *Id.* Blenke concluded that these varying results make "the

comparison between . . . encapsulation efficiency impossible if different measurement methods are used." Ex. 60 (Blenke) at 796. Therefore, the claim term "is invalid for indefiniteness . . . because read in light of the specification and the prosecution history, the patentee has failed to inform with reasonable certainty those skilled in the art about the scope of the invention. On this record, there is not reasonable certainty [regarding how encapsulation efficiency] should be measured . . . ." *Teva*, 789 F.3d at 1345.

IX. CONCLUSION

Moderna respectfully requests that its motions for summary judgment be granted.

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